

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

Case No. 1:17-md-2804

Judge Dan Aaron Polster

**CERTAIN NON-LITIGATING REMAINING DEFENDANTS’  
POSITION STATEMENT REGARDING PLAINTIFFS’ REQUEST FOR ARCOS DATA**

In accordance with the Court’s June 15, 2023 Order regarding the subpoena by the Plaintiffs Executive Committee (“PEC” or “Plaintiffs”) to the U.S. Drug Enforcement Administration (“DEA”) for production of updated ARCOS data, Dkt. 5072, the undersigned Non-Litigating Remaining Defendants (“Remaining Defendants”) submit this position statement. Remaining Defendants appreciate the Court’s provision of the PEC’s request and the DEA’s response, as well as its invitation to weigh in on these issues. Dkt. 5072 (“The Court is particularly interested in the views of non-settling MDL defendants as to their need for updated ARCOS data for litigation and/or settlement purposes.”)

For the reasons set forth below, Remaining Defendants join DEA and oppose the release of updated ARCOS data. First, additional ARCOS data not only is unnecessary and unhelpful to resolution efforts, but production of such data would affirmatively disrupt and delay potential resolution. Second, Remaining Defendants object to the PEC’s suggestion that they intend to use updated ARCOS data to pursue an expansion of the MDL by amending existing complaints or filing new lawsuits.

**I. Updated ARCOS data is unnecessary for resolution and will disrupt ongoing or potential discussions.**

Remaining Defendants disagree with the PEC's contention that updated ARCOS data is "important for settlement purposes with regard to the remaining Defendants." PEC Letter Mot. at 2, Dkt. 5072-1. To the extent ARCOS data—and Plaintiffs' use of that data—is at all relevant or useful for settlement purposes (which Remaining Defendants contest), Plaintiffs can use the data they already have to advance any resolution efforts with Remaining Defendants, just as they did with previous defendants. Indeed, Plaintiffs have negotiated nearly a dozen nationwide settlements and many more state and subdivision-specific resolutions with other defendants in the opioids litigation in recent years—including several within the last few months. Plaintiffs also have negotiated state and subdivision-specific resolutions with certain Remaining Defendants—demonstrating that settlements are possible without updated ARCOS data. There is no reason to assume that more recent ARCOS data would somehow be needed as to Remaining Defendants, particularly given that the *prior* ARCOS data disclosure was the primary basis on which many Remaining Defendants were named in MDL cases.<sup>1</sup>

Moreover, disclosure of additional ARCOS data would only disrupt and delay any resolution efforts. DEA has described the significant burden of compiling, producing, and validating millions of records in the ARCOS data and has indicated how time-consuming it expects any such process to be. *See* DEA Letter Mot. at 4–5 (June 15, 2023), Dkt. 5072-2; *id.* at Ex. B, Howard Decl. From there, release of updated ARCOS data will trigger costly efforts to review and interpret the data, including through retained experts. Remaining Defendants anticipate that

---

<sup>1</sup> Further, Plaintiffs can request (and have requested) information directly from Remaining Defendants that can be used to assess Remaining Defendants' involvement (if any) in the market during more recent timeframes.

Plaintiffs will ask Dr. McCann (or a similar retained consultant) to extend the prior analysis of the ARCOS data and prepare additional years of market share calculations based on the new data. The Court has recognized that this process took substantial time and resources the first time around.<sup>2</sup> *See* Ongoing Common Benefit Order at 10, Dkt. 4428 (May 9, 2022) (acknowledging that efforts to make ARCOS data available in a “meaningful and useable form to all parties” required “great expense” as the PEC “organized, programmed, analyzed, and reported” the DEA’s data, which was produced in “essentially raw form”). DEA already has noted the lack of reliability associated with this data. *See* DEA Letter Mot. at 5 (June 15, 2023), Dkt. 5072-2 (noting the likelihood of numerous anomalies in the data). Remaining Defendants would have to similarly engage consultants to review and interpret any new updated ARCOS data and any subsequent PEC analysis. Remaining Defendants further expect, based on their experience with the PEC’s prior ARCOS analysis, that the parties would need to devote resources toward resolving disagreements about the meaning of the data. This entire process would divert significant time and resources and undoubtedly delay the prospect of any meaningful resolution discussions by many months.

**II. Allowing the production of updated ARCOS data would be counterproductive, because Plaintiffs have said they will use the data to amend their MDL complaints and to file new lawsuits.**

Plaintiffs revealed at the June 14, 2023 status conference that they may seek leave to amend their complaints in the MDL or to file new and additional lawsuits following any production of updated ARCOS data. Remaining Defendants object to opening a new process—six years into litigation in the MDL—that threatens to further expand an MDL the Court has indicated it is

---

<sup>2</sup> The PEC also has previously described its costly efforts to review DEA ARCOS data, including “retain[ing] a firm who specialized in extracting and analyzing the data into a usable and understandable format,” at a cost exceeding \$1 million. *See* Declaration of Peter H. Weinberger, Dkt. 3352-4 (June 24, 2020).

looking to wind down, as well as to compromise any potential resolution discussions by rendering the litigation landscape a constantly moving target.<sup>3</sup>

To allow the production of updated ARCOS data that is intended to be used to amend complaints or to file new complaints—or even to allow the threat of such complaints to be used by Plaintiffs for perceived settlement leverage—would be at cross-purposes to any resolution process for the Remaining Defendants. Plaintiffs’ prior interpretation of ARCOS data to calculate market share remains a critical issue in contention;<sup>4</sup> the release of updated ARCOS data and the filing of additional lawsuits putatively based on that data would only make things worse. What the parties need for any potential resolution process to be productive is the same thing the Court needs in order to wind down this MDL: stability and narrowed issues, not a chaotic, shifting litigation landscape.

Ever since the Court first turned its attention to defendants not previously involved in MDL bellwether tracks, the stated goal has been to narrow claims, eliminate parties, and resolve cases where possible. Allowing Plaintiffs to access new data they intend to use to further *expand* the MDL would be counterproductive. At the outset, for example, the Court asked Plaintiffs to indicate how serious they were about pursuing claims against Remaining Defendants. *See* Order, Dkt. 4380 (Apr. 21, 2022) (“The status reports shall include notice of how and whether Plaintiffs intend to proceed against each of the above-listed Defendants”). Most Plaintiffs did not comply.

---

<sup>3</sup> Remaining Defendants reserve all rights to object to any forthcoming motion for leave to amend, as well as any proposed process to amend complaints in the MDL based on updated ARCOS data or, in the alternative, to suggest limitations on the use of ARCOS data to amend complaints.

<sup>4</sup> Remaining Defendants dispute and reserve all rights with respect to the ways in which Plaintiffs have used prior disclosures of ARCOS data to date, including without limitation (1) the fundamental idea that any particular level of market share can be used as a proxy for showing wrongful conduct and (2) the specific market share calculations advanced by the PEC.

The Court also sought the parties' input about how to winnow remaining cases and claims. *See* Order, Dkt. 4742 (Nov. 9, 2022). Once again, most Plaintiffs took no meaningful steps to do so. Even when Remaining Defendants identified substantive issues with the alleged market-share basis on which they were named, and requested the PEC's assistance in securing voluntary dismissals in cases in which defendants have zero or *de minimis* market share, very few dismissals occurred. The Court and the parties need renewed efforts to narrow the remaining cases—not to expand them in ways that likely will add years to the litigation.

That is particularly so because Plaintiffs' prior use of putative ARCOS market share data as a proxy for liability has expanded these lawsuits to a slew of new defendants without any allegation of wrongful conduct. As various Remaining Defendants have highlighted over the last several months in status reports and at status conferences, nearly all the cases naming the Remaining Defendants have not been plausibly alleged. In bringing many Remaining Defendants into the fray, Plaintiffs previously relied solely upon the Remaining Defendants' status as a participant in the market.<sup>5</sup> Setting aside the fact that the mere presence of product in the market is not indicative of liability under any formulation of public nuisance, the prospect of Plaintiffs now seeking to do that yet *again*—at a time when the goal should be to limit claims and parties—is untenable and will undermine resolution efforts.

---

<sup>5</sup> In November 2018, the Court allowed Plaintiffs to amend complaints on the basis of market share reports reflecting the names of all labelers (as identified by NDC code) who manufactured and/or labeled more than five percent of the market share of opioids distributed in the relevant county or county-equivalent in at least three of the nine years available in ARCOS data. *See* Order Regarding Plaintiff's Motion for Modification of CMO-1, Dkt. No. 1106 (Nov. 8, 2018). This amended complaint process followed the Court's order of production of prior ARCOS data, which the Court indicated would be its last. Third Order Regarding ARCOS Data, Dkt. 668 at 2 (June 26, 2018) ("This directive for release of additional ARCOS data will be the *last one* made by the MDL Court.") (emphasis added). Plaintiffs' interpretation of the ARCOS data resulted in several hundreds of lawsuits against newly added defendants.

\*\*\*

For the foregoing reasons, Remaining Defendants oppose the production of further ARCOS data.

Dated: June 29, 2023

Respectfully submitted,

/s/ Paul J. Cosgrove

Paul J. Cosgrove  
ULMER & BERNE LLP  
312 Walnut Street, Suite 1400  
Cincinnati, Ohio 45202  
Phone: (513) 698-5000/Fax: (513) 698-5001  
pcosgrove@ulmer.com

Joshua A. Klarfeld  
Georgia Hatzis  
ULMER & BERNE LLP  
1660 W. 2nd Street, Suite 1100  
Cleveland, OH 44113  
Phone: (216) 583-7000/Fax: (216) 583-7001  
jklarfeld@ulmer.com  
ghatzis@ulmer.com

*Attorneys for Defendants Amneal Pharmaceuticals  
LLC, and Amneal Pharmaceuticals of New York,  
LLC*

/s/ Rebecca C. Mandel

Adam K. Levin  
Rebecca C. Mandel  
HOGAN LOVELLS US LLP  
555 13th St. NW  
Washington, DC 20004  
Telephone: (202) 637-5600  
Facsimile: (202) 637-5910  
adam.levin@hoganlovells.com  
rebecca.mandel@hoganlovells.com

*Counsel for the Mylan Defendants*

/s/ Christopher B. Essig

Christopher B. Essig  
Scott M. Ahmad  
Reid F. Smith  
WINSTON & STRAWN LLP  
35 W. Wacker Drive  
Chicago, IL 60601  
Phone: (312) 558-5600  
cessig@winston.com  
sahmad@winston.com  
rfsmith@winston.com

*Attorneys for Defendant  
Hikma Pharmaceuticals USA Inc.  
f/k/a West-Ward Pharmaceuticals Corp.*

/s/ Thomas E. Rice

Thomas E. Rice  
BAKER STERCHI COWDEN & RICE LLC  
2400 Pershing Road, Suite 500  
Kansas City, MO 64108  
Telephone: (816) 471-2121  
Facsimile: (816) 472-0288  
rice@bakersterchi.com

*Counsel for Defendant KVK-Tech, Inc.*

/s/ Clifford F. Kinney Jr.

Clifford F. Kinney, Jr. (WVSB #6220)  
Spilman Thomas & Battle, PLLC  
P.O. Box 273  
Charleston, WV 25321  
Phone: 304-340-3844  
Fax: 304-340-3801  
Email: ckinney@spilmanlaw.com

*Counsel for Keysource Medical, Inc.*

/s/ Kevin M. Sadler

Kevin M. Sadler  
Baker Botts L.L.P.  
1001 Page Mill Rd., Building One Suite 200  
Palo Alto, California 94304

Telephone: (650) 739-7518  
kevin.sadler@bakerbotts.com

Scott D. Powers  
Baker Botts L.L.P.  
401 South 1st Street, Suite 1300  
Austin, Texas 78704  
Telephone: (512) 322-2678  
scott.powers@bakerbotts.com

*Counsel for Defendant Assertio Therapeutics, Inc.  
f/k/a Depomed, Inc.*

/s/ James W. Matthews

James W. Matthews (MA BBO # 560560)  
Katy E. Koski (MA BBO #650613)  
**FOLEY & LARDNER LLP**  
111 Huntington Avenue  
Boston, MA 02199  
Telephone: (617) 342-4000  
jmatthews@foley.com  
kkoski@foley.com

*Attorneys for Apotex Corp.*

/s/ Craig M. Reiser

Craig M. Reiser  
AXINN, VELTROP & HARKRIDER LLP  
114 West 47th Street  
New York, New York 10036  
212.728.2200  
212.728.2201 (fax)  
creiser@axinn.com

*Counsel for Defendant Alvogen, Inc.*

/s/ Jennifer P. Richnafsky

Christopher J. Davis  
Jennifer P. Richnafsky

**SHERARD GERMAN & KELLY, PC**  
The Oliver Building



535 Smithfield Street, Ste. 300  
Pittsburgh, Pennsylvania 15222  
Tel: (412) 355-0200  
Fax: (412) 261-6221  
Chris.Davis@sgkpc.com  
Jennifer.Richnafsky@sgkpc.com

*Attorneys for Defendants Value Drug Company and  
Value Specialty Pharmacy*

/s/ Lauren S. Colton

**HOGAN LOVELLS US LLP**  
100 International Drive, Suite 2000  
Baltimore, MD 21202  
Tel: (410) 659-2733  
lauren.colton@hoganlovells.com

*Attorney for Defendant Zydus Pharmaceuticals  
(USA) Inc.*

/s/ Allen M. Lopus

Allen M. Lopus  
Clark Hill, PLC  
One Oxford Centre, 14<sup>th</sup> Floor  
301 Grant Street  
Pittsburgh, PA 15219  
Phone: (412) 394-7713  
Fax: (412) 394-2555  
alopus@clarkhill.com

*Counsel for Defendant TopRx, LLC*

**TROUTMAN PEPPER HAMILTON  
SANDERS LLP**

/s/ Michael G. Connelly

Michael G. Connelly (PA Bar No. 79991)  
501 Grant Street, Suite 300  
Union Trust Building  
Pittsburgh, PA 15219-4429  
(412) 454-5810  
michael.connelly@troutman.com

Hyung P. Steele (PA Bar No. 91294)  
3000 Two Logan Square  
Eighteenth & Arch Streets  
Philadelphia, PA 19103-2799  
215.981.4000  
christopher.wasson@troutman.com  
hyung.steele@troutman.com

*Counsel for Sun Pharmaceutical Industries, Inc.*

/s/ Jeffrey A. Kennard

Jeffrey A. Kennard  
Cameron E. Grant  
SCHARNHORST AST KENNARD GRIFFIN, PC  
1100 Walnut, Suite 1950  
Kansas City, MO 64106  
Tel: (816) 268-9400  
Fax: (816) 268-9409  
Email: jkennard@sakg.com  
cgrant@sakg.com

*Counsel for Hy-Vee, Inc.*

/s/ Adam Cohen

Adam Cohen  
Jim Walden  
Walden Macht & Haran LLP  
250 Vesey Street, 27<sup>th</sup> Floor  
New York, NY 10281  
Tel: (212) 335-2030  
acohen@wmhlaw.com  
jwalden@wmhlaw.com

*Attorneys for Defendant Morris & Dickson Co., LLC*

**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing was electronically filed and served upon counsel of record by operation of the Court's CM/ECF System on June 29, 2023.

/s/ Paul J. Cosgrove